



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#16/183  
55  
10-28-03

Applicant: Gholam-Reza Zadno-Azizi, *et al.*

Serial No.: 10/081,569

Conf. No.: 4156

Filed: February 21, 2002

For: *BODY FLUID FLOW CONTROL  
DEVICE*

Art Unit: 3738

Examiner: Urmi Chattopadhyay

Commissioner for Patents  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

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**NOTICE UNDER 37 C.F.R. § 1.612 FOR LIMITED  
ACCESS TO DECLARATION PURSUANT TO 37 CFR  
§1.131**

Dear Sir:

Notice is hereby given that the attached Declaration under 37 C.F.R. § 1.131 by Dr. Gholam-Reza Zadno-Azizi, John S. Ford, and April Marano-Ford, is being filed under the limited access provisions of 37 C.F.R. § 1.612. Accordingly, the aforementioned Declaration is available for inspection by an opposing party only after the preliminary motions under 37 C.F.R. § 1.633 are decided.



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**DECLARATION PURSUANT TO 37 CFR §1.131**

We, Gholam-Reza Zadno-Azizi, John S. Ford, and April Marano-Ford,  
declare as follows:

1. We are co-inventors of the subject matter that is disclosed and claimed in U.S. Patent Application 10/081,569 (the Instant Application).
2. We are aware of the U.S. Patent and Trademark Office rejections of claims 20-25 of the Instant Application over U.S. Patent No. 5,894,965 to Knapp *et al.*, filed August 28, 1997 and issued November 16, 1999.
3. We have reviewed claims 20-25 of the Instant Application, and we are the inventors of the subject matter of those claims.
4. We conceived of the invention claimed in claims 20-25 prior to August 28, 1997. We proceeded with due diligence from prior to August 28, 1997 to the filing date of U.S. Patent Application Serial No. 08/931,552, which

describes the invention claimed in claims 20-25 and which was filed on September 16, 1997.

5. U.S. Patent Application Serial No. 08/931,552, filed September 16, 1997, now U.S. Patent No. 5,954,766, is the parent of U.S. Patent Application Serial No. 09/397,218, filed September 16, 1999, which is the parent of the Instant Application.

6. We provide below the attached Exhibits that cover a period from prior to August 28, 1997 through the filing of U.S. Patent Application Serial No. 08/931,552 on September 16, 1997. The Exhibits demonstrate that we conceived of a pulmonic flow control device and a pulmonic fluid-flow control system as defined in claims 20-25 prior to August 28, 1997, and that we proceeded with due diligence from prior to August 28, 1997 to the filing date of U.S. Patent Application Serial No. 08/931,552. All of the exhibits are dated prior to August 28, 1997. All dates have been masked out of the exhibits.

7. Exhibit 1 includes a 3-page invention disclosure that we prepared prior to August 28, 1997. As recited in claim 20 of the Instant Application, page 1 of the invention disclosure includes a written description of a one-way valve configured to restrict fluid flow, and pages 2 and 3 of the invention disclosure include drawings of an exemplary one-way valve dimensioned for pulmonary placement. As recited in claims 21 and 24 of the Instant Application, the drawing on page 3 is labeled to show that the one-way valve has an outer diameter of 0.349 inches..

8. Exhibit 2 includes two pages of sketches that we prepared prior to August 28, 1997. As recited in claims 22 and 25 of the Instant Application, page

1 includes a sketch of a valve having a valve body and a valve slit through which fluid can flow.

9. Exhibit 3 includes a one-page sketch that we prepared prior to August 28, 1997. As recited in claim 23 of the Instant Application, the sketch shows an elongate passage and outer sheath for positioning a valve.

10. Prior to August 28, 1997, we retained John D. McConaghy, a patent attorney with the law firm Lyon & Lyon, to prepare a patent application based at least in part on the contents of Exhibits 1, 2, and 3.

11. During a period prior to August 28, 1997 to the filing date of U.S. Patent Application Serial No. 08/931,552, Mr. McConaghy diligently prepared and provided to us at least one draft of a patent application describing the pulmonic fluid-flow control device and fluid flow control system of claims 20-25. We diligently reviewed the patent application and provided comments to Mr. McConaghy.

12. On September 16, 1997, Mr. McConaghy filed U.S. Patent Application Serial No. 08/931,552, which describes the pulmonic fluid-flow control device and fluid flow control system of claims 20-25.

We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

**Response to Office Action**  
**Gholam-Reza Zadno-Azizi, *et al.***  
**U.S.S.N. 10/081,569**

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Date

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Gholam-Reza Zadno-Azizi

\_\_\_\_\_  
Date

\_\_\_\_\_  
John S. Ford

\_\_\_\_\_  
Date

\_\_\_\_\_  
April Marano-Ford